CORPORATE INTEGRITY AGREEMENT between the Office of Inspector General of the Department of Health and Human Services and

Sharp Memorial Hospital

I. PREAMBLE

Sharp Memorial Hospital ("Hospital") hereby agrees to enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Hospital, its physicians, employees, and other health care professionals, as well as all third parties which Hospital engages to act as billing or coding agents or consultants for Hospital. On or about this date, Hospital is entering into a settlement agreement with the United States and this CIA is incorporated by reference into that settlement agreement.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by Hospital under this CIA shall be three (3) years from the date of execution of this CIA (unless otherwise specified).

III. CORPORATE INTEGRITY OBLIGATIONS

A. Compliance Officer and Compliance Committee

Within 120 days after the execution of this CIA, Hospital shall designate a Compliance Officer who shall be responsible for developing, implementing, monitoring, adapting, reporting on, and certifying compliance with, policies and procedures and practices designed to ensure compliance with the requirements set forth in this CIA, and with the requirements of Medicare, Medicaid, and all other Federal health care programs. The Compliance Officer shall be a member of senior management of Hospital (i.e., not subordinate to Hospital's general counsel, CFO, or similar officer) and shall make regular (at least quarterly) reports regarding compliance matters directly to the Hospital CEO and/or to the Board of Directors of Hospital.

Corporate Integrity Agreement: Sharp Memorial Hospital

Within 120 days after the execution of this CIA, Hospital shall also appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers (e.g., senior executives of each major department such as billing, clinical, human resources, audit, operations, etc). The Compliance Committee shall support the Compliance Officer in fulfilling his or her responsibilities. The names and positions of the Compliance Committee members shall be included in the Annual Report.

B. Code of Conduct and Policies and Procedures

1. Code of Conduct

Within 120 days after the execution of this CIA, Hospital shall establish a Code of Conduct. The Code of Conduct shall, at a minimum, set forth:

- a. Hospital's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures, or instructions otherwise communicated by HCFA (or any other appropriate regulatory agency) or its agents;
- b. The responsibility of all of Hospital's employees, contractors, and agents to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Hospital's own policies and procedures (including the requirements of this CIA);
- c. The responsibility of all of Hospital's employees, contractors, and agents to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or with Hospital's own policies and procedures;
- d. The possible consequences to both Hospital and to any employee, contractor, or agent of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Hospital's own policies and procedures and of failure to report such non-compliance; and
- e. The right of all employees, contractors, and agents to use the Confidential Disclosure Program (as described in section III.F, below) and Hospital's commitment to confidentiality and non-retaliation with respect to disclosures.

The Code of Conduct shall be distributed by Hospital individually to all employees, all contractors, and all other individuals with any responsibility, directly or

indirectly, for the billing, documentation, or provision of health care services, including but not limited to all personnel with responsibilities pertaining to coding and physicians with privileges. Within 120 days after the execution of this CIA, or within one week after the commencement of the individual's relationship with Hospital (e.g., employment or contract), whichever is later, and annually thereafter, each individual who should receive the Code of Conduct shall certify in writing that he or she has read and understands the Code of Conduct. Hospital shall keep a copy of these certifications on file for at least one year after the completion of the period of compliance obligations mandated by this CIA. Hospital shall make all reasonable efforts to obtain such certifications from each and every non-employee physician with staff privileges at Hospital, and to the extent that Hospital cannot obtain such certifications from all such physicians, Hospital shall report to OIG all efforts made to convince the non-employee physicians to certify that he or she has read and understands the Code of Conduct. Hospital shall report to OIG the percentage of physicians with staff privileges who have completed this certification.

2. Policies and Procedures

Within 120 days after the execution of this CIA, Hospital shall develop and effectively implement written Policies and Procedures regarding compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of Medicare, Medicaid, and all other Federal health care programs. The Policies and Procedures shall specifically require that all diagnosis codes submitted for claims purposes to Medicare, Medicaid, or any other Federal health care program be properly supported by documentation by the treating physician in the patient's medical record. The Policies and Procedures shall require that all inpatient claims with a principal diagnosis code of 482.89 (or any successor to this code) intended for submission to Medicare shall first be subject to pre-billing review to ensure that the diagnosis code was properly assigned. The Policies and Procedures shall include disciplinary guidelines and methods for employees to make complaints and notifications about compliance issues to Hospital management through the Confidential Disclosure Program required by section III.F. Hospital shall update the Policies and Procedures at least annually and more frequently as appropriate.

C. Training and Education

1. General Training

Hospital shall provide and require at least two (2) hours of general training to each and every employee of Hospital with responsibility for the provision, documentation, or billing of inpatient hospital services. This general training shall: (a) cover Hospital's Code of Conduct; (b) reinforce the need for strict compliance with the applicable statutes, regulations, policies, procedures, program guidelines, and Hospital's Policies and Procedures; and (c) advise employees that any failure to comply may result in

disciplinary action. Employees required to receive the general training shall receive the training described above within 120 days after the execution of this CIA or within two (2) weeks after the beginning of their employment by Hospital, whichever is later. Annually thereafter, Hospital shall provide and require one (1) hour of such general training to such individuals.

Hospital shall make the training regarding the topics described in this section available to physicians with staff privileges and use its best efforts to encourage their attendance and participation.

2. Coding Training

In addition to the general training described above, Hospital shall provide and require at least five (5) hours of coding training to each and every person involved in the assignment of diagnosis or procedure codes for billing Medicare, Medicaid, or any other Federal health care programs. This coding training shall cover applicable statutes. regulations, policies, procedures, and program guidelines for Medicare, Medicaid, and all other Federal health care programs, as well as Hospital's own Policies and Procedures. Employees required to receive the coding training shall receive the training described above within 120 days after the execution of this CIA or within two (2) weeks after the beginning of their employment by Hospital, whichever is later. Annually thereafter, Hospital shall require and provide three (3) hours of the above described coding training to such individuals. If an newly employed individual has any responsibility for the assignment of diagnosis or procedure codes prior to his or her completion the coding training as required by this section, all of his or her work regarding the assignment of diagnosis or billing codes must be reviewed by an individual who has completed all required training. Similarly, if an existing employee fails to complete his or her coding training by the deadlines as set forth in this section, all of his or her work regarding the assignment of diagnosis or billing codes must be reviewed by an individual who has completed all required training within the time constraints required by this section.

Hospital shall make the training regarding the topics described in this section available to physicians with staff privileges and use its best efforts to encourage their attendance and participation.

D. Audits

Prior to the first anniversary of the execution of this CIA, Hospital shall retain a third-party to perform an audit, in accordance with generally accepted principles of statistical validity and accuracy, designed to ensure compliance with the written Policies and Procedures described in III.B.2, with this CIA, and with all applicable federal and state health care statutes, regulations, policies, procedures, and program guidelines. Annually thereafter, Hospital shall perform, or retain a third-party to perform, the same types of audits. Such audits shall examine a 12 month period and should cover areas of

potential fraud, abuse, or waste, as identified by Hospital or by the government, (see, e.g., OIG's Compliance Guidelines for Hospitals, 63 Federal Register 8987 (February 23, 1998)), and shall focus particular attention on coding and the activities of physicians and personnel involved in the identification and coding of diagnoses for the purpose of billing Medicare, Medicaid, or any other Federal health care program. The audits must be retained by Hospital for at least one year after the completion of the period of compliance obligations mandated by this CIA.

E. Disclosures

1. Disclosure of Material Deficiencies

If, as a result of the audits performed pursuant to section III.D, above, or through any other means, Hospital discovers any billing, coding or other policies, procedures and/or practices that result in a material deficiency, Hospital shall notify the appropriate payor (e.g, Medicare fiscal intermediary or carrier) within 30 days of discovering the deficiency and shall take remedial steps within 60 days (or such additional time as may be agreed to by the payor) to correct the problem, including steps to prevent the deficiency from reoccurring. The notice to the payor should state that the repayment is being made in accordance with the terms of this CIA and should include: (a) the methodology by which the overpayment was determined; (b) any claim specific information used to determine the overpayment; (c) the amount of the overpayment; and (d) the date of the check and check number (or electronic transaction number) on which the overpayment was repaid.

Contemporaneous with Hospital's notification to the payor as provided above, Hospital shall notify OIG of: (a) all of the information provided to the payor in returning the overpayment; (b) the name and the address of the payor where the overpayment was sent; (c) Hospital's findings concerning the material deficiency; (d) Hospital's actions to correct such material deficiency; and (e) any further steps the Hospital plans to take to address such material deficiency and prevent it from reoccurring.

For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to a Federal health care program; (ii) conduct or policies that clearly violate Federal health care program statutes, regulations, or program directives (e.g., for Medicare issuances by HCFA, fiscal intermediaries, and carriers); or (iii) serious quality of care implications for federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

2. Disclosure of Overpayments

If Hospital learns of any overpayment, regardless of its size and regardless of whether it results from a material deficiency, Hospital shall promptly (but in no event

later than 60 days after discovering the overpayment), bring such overpayment to the appropriate payor's attention, make appropriate refunds and take any steps necessary to prevent similar future overpayments.

3. Violations of Law

If Hospital discovers from any source credible evidence of misconduct relating to any Federal health care program and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law, then Hospital shall promptly report the probable violation of law to the appropriate governmental authorities (including the Department of Justice and OIG with respect to Medicare and Medicaid violations giving rise to causes of actions under criminal, civil, or administrative false claims statutes) within a reasonable period, but not more than fifteen days after determining that there is credible evidence of a violation. When reporting possible violations of law, Hospital shall provide all evidence relevant to the violation of law and potential cost impact. Hospital shall thoroughly investigate such possible violation of law, and once the investigation is completed, Hospital shall notify the appropriate governmental authorities of the outcome of the investigation, including a description of the impact of the violation on the operation of applicable Federal health care programs or their beneficiaries. If the investigation ultimately reveals that criminal, civil, or administrative violations have occurred, the appropriate governmental authorities should be notified immediately.

F. Confidential Disclosure Program

Within 120 days after the execution of this CIA, Hospital shall establish a Confidential Disclosure Program enabling Hospital employees, agents and contractors to communicate about compliance issues to the Compliance Officer. The Confidential Disclosure Program shall provide methods, such as a toll-free compliance "hotline," for Hospital employees, agents, and contractors to disclose any practices or procedures with respect to Medicare, Medicaid, or any other Federal health care program, alleged by the individual to be inappropriate, to the Compliance Officer or to some other person who is not in the reporting individual's chain of command.

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Hospital shall use intake procedures designed to elicit all relevant information from individuals reporting alleged misconduct. For any disclosure that is sufficiently specific that it reasonably (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides opportunity for the taking of corrective action, Hospital shall require the internal review of the allegations set forth in such disclosure and ensure that proper follow-up is conducted. Hospital shall make a good faith preliminary inquiry into the allegations set forth in every disclosure to ensure that it

has obtained all of the information necessary to determine whether it should conduct an internal review as provided above.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record of each allegation received, status of the investigation of the allegation, and any corrective action taken in response to the investigation. The Compliance Officer shall maintain all documentation related to information in the log and make such documents available for inspection by OIG upon request. The Compliance Officer shall keep a copy of this log and related documentation on file for at least one (1) year after the completion of the period of compliance obligations mandated by this CIA.

G. Ineligible Persons

- 1. Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.
- 2. Screening Requirements. Hospital shall not hire, engage as a contractor, or otherwise use the services of any Ineligible Person. To prevent hiring of or contracting with any Ineligible Person, Hospital shall screen all prospective employees, agents and contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/progorg/oig, and formerly known as the "HHS/OIG Cumulative Sanctions Report") (these lists and reports will hereinafter be referred to as the "Exclusion Lists").
- 3. Review and Removal Requirement. Within ninety (90) days of the effective date of this CIA, Hospital will review its list of current employees, agents and contractors against the Exclusion Lists. If Hospital has notice that an employee, agent or contractor has become an Ineligible Person, Hospital shall remove such person from responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.
- 4. Pending Charges and Proposed Exclusions. If Hospital has notice that an employee, agent or contractor is charged with a criminal offense related to any Federal

health care program, or is suspended or proposed for exclusion during his or her employment or contract with Hospital, within 10 days of receiving such notice Hospital will remove such person from responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

IV. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the execution of this CIA, Hospital shall submit a written report to OIG summarizing the status of implementation of the requirements set forth in this CIA. This Implementation Report shall include:

- 1. The name and position description of the Compliance Officer and names of members of the Compliance Committee as required by section III.A;
- 2. A copy of the Code of Conduct and written Policies and Procedures required by section III.B; and
- 3. A description of the training programs implemented pursuant to section III.C and a summary of the activities undertaken in furtherance of the training programs, including schedules and topic outlines from the training sessions.

B. Annual Reports

Hospital shall submit to OIG Annual Reports with respect to the status and finding of its compliance activities. The Annual Reports shall be received by OIG no later than 30 days after the first, second, and third anniversary dates of the execution of this CIA. The Annual Reports shall include:

- 1. Any change in the identity or position description of the Compliance Officer or any change in the identity of the members of the Compliance Committee described in section III.A;
- 2. Any changes or amendments to the Code of Conduct and Policies and Procedures required by section III.B;
- 3. A description of any changes in the training programs implemented pursuant to section III.C and a summary of the activities undertaken in furtherance of the training programs, including schedules and topic outlines for the training sessions;
- 4. A description of the audits conducted pursuant to section III.D and the audit results, including a copy of the audit reports;

- 5. A list of all disclosures of material deficiencies, overpayments, and possible violations of law as required by section III.E;
- 6. A description of the disclosures received and actions taken by Hospital pursuant to section III.F and a copy of the confidential disclosure log required by that section;
- 7. A description of any personnel action taken by Hospital as a result of the obligations set forth in section III.G;
- 8. A description of any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Hospital has committed a crime or has engaged in fraudulent activities;
- 9. A report of the aggregate overpayments that have been returned to Medicare, Medicaid, and all other Federal health care program that were discovered as direct or indirect result of the corporate integrity provisions in this CIA (this report must include a detailed description of how the overpayments were calculated, and the overpayments must be broken down into the following categories: Medicare, Medicaid (reporting each state separately), and other Federal health care programs); and
- 10. A certification by the Compliance Officer verifying that Hospital is in compliance with all of the requirements of this CIA.

V. DOCUMENT AND RECORD RETENTION

Hospital shall maintain for inspection all documents and records relating to reimbursement from Federal health care programs or compliance with this CIA until the fourth anniversary of the execution of this CIA or until otherwise required to retain such records, whichever is later.

VI. OIG RIGHTS OF INSPECTION

In addition to any other rights OIG may have by statute, regulation, contract or pursuant to this CIA, OIG or its duly authorized representative(s) may examine all non-privileged books, records, and other Hospital documents and supporting materials for the purpose of verifying and evaluating Hospital's compliance with the terms of this CIA and with the requirements of the Medicare, Medicaid and other Federal health care programs. The documents described above shall be made available by Hospital at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its authorized representative(s) may interview any of Hospital's employees who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG. Each employee shall be advised by the OIG or any duly authorized

representative prior to any such interview that the employee may elect to be interviewed with or without an attorney or a representative of Hospital present. Each employee shall be advised that he or she is not represented by Hospital's attorneys. Hospital agrees to assist OIG in contacting and arranging interviews with such employees upon OIG's request, such as by making all employees available for interview upon OIG's request, and arranging for a location on Hospital premises within normal business hours for such an interview to take place. If Hospital so assists in arranging for such interviews and does nothing to discharge employees from participating in such interviews, then the decision of any employee not to be interviewed by any government representative shall not be deemed a breach of this CIA.

VII. OIG RIGHTS OF AUDIT AND REVIEW

In the event that OIG determines that it is necessary to conduct an independent audit or review to determine whether or the extent to which Hospital is complying with its obligations under this CIA, Hospital agrees to pay for the reasonable cost of any such audit or review by OIG or any of its agents.

VIII. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Hospital and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions:

- 1. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the obligation became due) for each day Hospital fails to have in place any of the following during the entire period beginning 120 days after the execution of this CIA and concluding at the end of the corporate integrity period required by this CIA:
 - a. A Compliance Officer;
 - b. A Compliance Committee;
 - c. A written Code of Conduct;
 - d. Written Policies and Procedures;
 - e. A general training program;
 - f. A coding training program; and
 - g. A Confidential Disclosure Program.

- 2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the obligation became due) for each day Hospital fails meet any deadline set forth in section IV to provide the Implementation Report or the Annual Report.
- 3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the failure to comply began) for each day Hospital:
 - a. hires, enters into a contract with, or otherwise uses the services of an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which Hospital can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person);
 - b. employs, contracts with, or otherwise uses the services of an Ineligible Person and that person: (i) has responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which Hospital can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person); or
 - c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after Hospital received notice of the relevant matter or after the resolution of the matter).
- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue 10 days after the date that OIG provides notice to Hospital of the failure to comply) for each day Hospital fails to comply fully and adequately with any obligation of this CIA. In its notice to Hospital, OIG shall state the specific grounds for its determination that the Hospital has failed to comply fully and adequately with the CIA obligation(s) at issue. With respect to the

Stipulated Penalty provision described in this section VIII.A.4 only, OIG shall not seek a Stipulated Penalty if Hospital demonstrates to OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) Hospital has begun to take action to cure the failure to comply, (ii) Hospital is pursuing such action with due diligence, and (iii) Hospital has provided to OIG a reasonable timetable for curing the failure to comply.

B. Payment of Stipulated Penalties

1. Demand Letter

Upon finding that Hospital has failed to comply with any of the obligations described above in section VIII.A and determining that Stipulated Penalties are appropriate, OIG shall notify Hospital by certified mail of: (a) Hospital's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within 15 days of the date of the Demand Letter, Hospital shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section VIII.D. Failure to respond to the Demand Letter by doing one of the above within the required time shall constitute a material breach of this CIA.

2. Requests for Extensions

Hospital may submit a timely written request for an extension of time to perform any act or file a notification or report required by this CIA. Such requests for extensions shall be given due consideration by OIG. Notwithstanding any other provision in this CIA, if OIG grants the timely written request, Stipulated Penalties shall not begin to accrue unless and until Hospital fails to meet the deadline granted by the extension. Notwithstanding any other provision in this section, if OIG denies a timely written request, Stipulated Penalties shall not begin to accrue until two (2) business days following Hospital's receipt of OIG's written denial of such a request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or notification or report is due to be filed.

3. Form of Payment

Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section IX, below.

4. Independence from Material Breach

Except as noted in section VIII.B.1, above, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's determination that Hospital has materially breached this CIA, which decision shall be made at OIG's discretion and governed by the provisions in section VIII.C, below.

C. Exclusion for Material Breach of this CIA

1. Notice of Material Breach and Intent to Exclude

The Parties agree that a material breach of this CIA by Hospital constitutes an independent basis for Hospital's exclusion from participation in Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that Hospital has materially breached this CIA and that exclusion should be imposed, OIG shall notify Hospital by certified mail of: (a) Hospital's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude Letter").

2. Opportunity to Cure

Hospital shall have 35 days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to OIG's satisfaction that:

- a. Hospital is in full compliance with this CIA;
- b. The alleged material breach has been cured; or
- c. The alleged material breach cannot be cured within the 35-day period, but that (i) Hospital has begun to take action to cure the material breach; (ii) Hospital is pursuing such action with due diligence; and (iii) Hospital has provided to OIG a reasonable timetable for curing the material breach.

3. Exclusion Letter

If at the conclusion of the 35-day period (or other specific period as subsequently agreed by OIG and Hospital), Hospital fails to meet the requirements of section VIII.C.2 above, OIG may exclude Hospital from participation in the Medicare, Medicaid and all other Federal health care programs. OIG will notify Hospital in writing of its determination to exclude Hospital (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the dispute resolution provisions set forth in section VIII.D below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement health programs. If Hospital is excluded under the

provisions of this CIA, Hospital may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. Material Breach

A material breach of this CIA means: (a) a failure by Hospital to meet an obligation under this CIA where the failure has a significant adverse impact on the integrity of Medicare, Medicaid, or any other Federal health care program (for example, a failure to report a material deficiency (as defined in section III.E.1), take corrective action, and pay the appropriate refunds, as provided in section III.E); (b) repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section VIII.A; or (c) failure to respond to a Demand Letter as provided in section VIII.B.1.

D. Dispute Resolution

1. Review Rights

Upon OIG's delivery to Hospital of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Hospital shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and Departmental Appeals Board (DAB) in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 30 days of the date of the Exclusion Letter.

2. Review of Stipulated Penalties

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Hospital was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Hospital shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. For purposes of paying Stipulated Penalties under this CIA, and if Hospital chooses to seek review in lieu of curing the breach and paying the Stipulated Penalties as set forth above, the ALJ's decision shall trigger Hospital's obligation to pay. Thus, payment will be due 15 days after the date on which the ALJ issues the decision. Hospital's election of its contractual right to appeal to

the DAB shall not abrogate its obligation to make payment upon issuance of the ALJ's decision.

3. Review of Exclusion

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a breach of this CIA shall be: (a) whether Hospital was in material breach of this CIA; and (b) whether such breach was continuing on the date of the Exclusion Letter. Hospital shall have the burden of proving that it had met the requirements set forth in section VIII.C.2, above, within 35 days after the date of the Notice of Intent to Exclude Letter. For purposes of the exclusion herein agreed to in the event of material breach of this CIA, and if Hospital chooses to seek review of the exclusion, the ALJ's decision shall trigger the exclusion. Thus, in this situation, OIG may proceed with its exclusion of Hospital if and when the ALJ issues a decision in favor of OIG. Hospital's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Hospital upon the issuance of the ALJ's decision.

IX. NOTIFICATION AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this CIA, all notifications and reports required under the terms of this CIA shall be submitted to the entities listed below:

If to OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Telephone: (202) 619-2078

Telephone: (202) 619-2078 Facsimile: (202) 205-0604

If to Hospital:

Paul Belton
Vice President, Corporate Compliance Officer
Sharp Healthcare
3131 Berger Street
San Diego, CA 92123
Telephone: (619) 541-4015

Telephone: (619) 541-4015 Facsimile: (619) 541-4030

X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement into which this CIA is incorporated, Hospital and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns and transferees of Hospital.
- B. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one in the same agreement.
- C. This CIA shall become final, effective, and binding on the date the final signature is obtained on the Settlement Agreement.
- D. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA.
- E. The undersigned Hospital signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

On Behalf of Sharp Memorial Hospital

DANIEL GROSS

Chief Executive Officer Sharp Memorial Hospital

BYROŃ GROŚS

Hooper, Lundy & Bookman, Inc. Counsel for Sharp Memorial Hospital 7/7/99

DATE

On Behalf of the Office of Inspector General of the Department of Health and Human Services

LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

DATE